



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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October 17, 2001

WARNING LETTER 2002-NOL-04

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Thomas G. Snell, Owner
Mississippi Food Service, Inc.
6698 Lauderdale Road
Toomsuba, Mississippi 39364

Dear Mr. Snell:

We inspected your firm, located at 6698 Lauderdale Road, Toomsuba, Mississippi, on August 30, 2001, and found that you have serious deviations from Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your various ready-to-eat sandwiches are misbranded under Sections 403(a)(1), 201(n) and 403(i)(2) of the Act. Our advisory letter to your firm, dated September 9, 1998, called to your attention the necessity to list allergenic substances on your food product labels.

You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. You can also find information on labeling of allergens through links in FDA's Center for Food Safety and Applied Nutrition home page at www.cfsan.fda.gov.

The deviations observed were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for tuna salad sandwiches to control the food safety hazard of pathogen growth and toxin formation.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm does not fully monitor the following eight areas of sanitation: safety of water; condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food from adulterants; proper labeling, storage, and use of toxic compounds; control of employee health conditions; and, exclusion of pests.

- You must have an adequately trained or qualified individual to develop, reassess, and modify your HACCP plan and to perform record review to comply with 21 CFR 123.10. However, no individual at your firm has received seafood HACCP training.
- Your sausage and egg, bacon cheeseburger, and double chili cheeseburger sandwiches are misbranded within the meaning of Sections 403(a)(1) and 201(n) of the Act because their labels do not reveal that the sandwiches contain nonfat dried milk and soy flour (sausage and egg sandwich), and soy flour (bacon cheeseburger and double chili cheeseburger sandwiches), facts which are material to individuals who must avoid these substances due to allergenic reactions from their consumption. These sandwiches are also misbranded within the meaning of Section 403(i)(2) of the Act because they are fabricated from two or more ingredients, which themselves contain two or more ingredients that are not listed in the ingredient statement. For instance, the ingredients of the enriched rolls or buns, which include white flour, soy flour and wheat gluten, are not listed in the ingredient statements for your sandwiches.

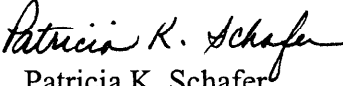
We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations and to prevent their recurrence. You may wish to include in your response documentation such as a HACCP plan for your tuna salad sandwiches, sanitation monitoring records, training certificates, corrected labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility nor your product label violations. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Ms. Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District